EXHIBIT C

Declaration of Kevin M. Kreutz, Deputy Attorney General for the General Litigation Division of the State Services and Litigation Section of the Office of the Tennessee Attorney General

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
KNOXVILLE DIVISION

STATES OF TENNESSEE, ALABAMA, ARKANSAS, GEORGIA, IDAHO, INDIANA, IOWA, LOUISIANA, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO, SOUTH CAROLINA, SOUTH DAKOTA, and WEST VIRGINIA, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF CIVIL RIGHTS, *Defendants.*	Civil Action No. 25-cv-00025

DECLARATION OF KEVIN M. KREUTZ

Pursuant to 28 U.S.C. § 1746, I, Kevin M. Kreutz, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Deputy Attorney General for the General Litigation Division (GLD) of the State Services and Litigation Section in the Office of the Tennessee Attorney General. The GLD division includes the Civil Medicaid Fraud (CMF) team. The CMF team's responsibilities include conducting and supervising investigations of Medicaid fraud pursuant to the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

3. As part of my responsibilities, I regularly review civil investigative demands ("CIDs") issued by the CMF team to entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"), seeking protected health information ("PHI") to investigate Medicaid fraud. CMF is authorized pursuant to Tenn. Code Ann. § 8-6-401 to issue CIDs. Federal regulation 45 C.F.R. § 164.512 permits covered entities to disclose PHI to our office in relation to our civil investigations and CIDs issued thereon

4. For example, CMF routinely requests billing data from health plan payers, such as health insurers or TennCare, Tennessee's Medicaid program. This data is used to vet leads on possible violations of the TMFCA and other related statutes. We frequently must request this information with imperfect knowledge of the possible misconduct being investigated because, before receiving the data, it is impossible to know the particulars of the investigation.

5. Indeed, obtaining medical records and PHI is crucial to the investigation, reporting, and litigation of healthcare fraud. It is a necessary component to proving various fraud schemes, including improper billing of care, rendering unnecessary or excessive services, billing for services that were not rendered, and other complex allegations.

6. Even after our office receives billing data, more investigation is generally required. To conduct investigations into healthcare fraud, it is necessary to issue CIDs, authorized under state law, to healthcare providers in order to obtain medical records and compare billing data with services rendered, as reflected in the medical records.

7. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the

"Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

8. The Final Rule has created compliance costs and barriers to investigation, impeding our investigation of healthcare fraud in Tennessee.

9. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information related to "reproductive health care," which it broadly defines as "health care … that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes," 45 C.F.R. § 160.103.

10. The Final Rule prohibits covered entities from disclosing PHI where it will be used for any of the following activities:

> (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
>
> (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

45 C.F.R. § 164.502(a)(5)(iii)(A).

11. If the covered entity concludes that one of these two conditions exists, it cannot disclose the requested information if it "reasonably determine[s]" that the "reproductive health care," at issue is either (1) "lawful under the law of the state in which such health care is provided under the circumstances in which it is provided," or (2) "protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided." *Id.* § 164.502(a)(5)(iii)(B).

12. In making that assessment, the Final Rule creates a presumption that reproductive health care provided by another person is lawful under (a)(5)(iii)(B)(1) or (2)—and so not subject to investigation by a State—unless the covered entity or business associate has either:

> (1) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided[, or];
>
> (2) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

Id. § 164.502(a)(5)(iii)(C).

13. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

14. Under the Final Rule, covered entities also must require attestations with a request for PHI that is potentially related to "reproductive health care" data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.*; *id.* § 164.512(f)(1)-(6)

15. Again, the Final Rule places the power to assess the lawfulness or validity of any PHI request or attestation entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information, as discretion whether to disclose the PHI remains with the covered entity. This means that in some cases the entity under investigation for fraud will have a veto on investigators' ability to obtain records necessary for their investigation.

16. My office has had to expend significant time and resources to determine how to comply with the Final Rule's attestation requirements because they are vague and overbroad. The Final Rule requires me and CMF in some cases to attest, upon pain of criminal penalty, to facts that are difficult or impossible to know at the preliminary stages of an investigation. If I have imperfect knowledge of an investigation such that I am unable to attest to the facts required under the Final Rule, we cannot meaningfully begin conducting investigations.

17. And given the criminal liability associated with HIPAA violations, my team will have to consult extensively with other divisions within the Attorney General's office to determine how, if possible, to comply with the Final Rule's attestation requirements without triggering potential criminal liability.

18. In addition to these compliance costs, the Final Rule is actively making it difficult or impossible to make data requests necessary to effectively investigate Medicaid fraud. We have paused all requests for billing data and medical records from covered entities until we know how the attestation requirement impacts our team's exposure to potential criminal liability.

19. We have also learned from other state agencies that covered entities have refused to disclose information without an attestation required by the Final Rule even in cases that have no obvious connection to "reproductive health care." We expect similar obstacles to our TMFCA investigations.

20. Because the Final Rule itself provides no recourse to contest a demand that is denied, my office will likely need to seek relief in a court of competent jurisdiction. Such a suit has the potential to sprawl into protracted and complicated litigation, giving rise to issues such as federal preemption and removal. And such a suit may require me to demonstrate in open court my theory of the case I am investigating without having adequate knowledge to do so. Any protracted

litigation may impact the amount of money the State may recoup from a viable fraud investigation because it may push some fraudulent activity outside of the relevant statute of limitations.

21. Ultimately, the Final Rule is complicating my team's duty and ability to investigate Medicaid fraud. Because of the Final Rule, fraud investigations that I am undertaking are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is impacting my strategic investigative decisions. For those reasons, the Final Rule is impacting the public health and safety of the State of Tennessee because it is delaying, impeding, and deterring viable fraud investigations.

Date: February 7, 2025